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SOUTHERN DISTRICT OF CALIFORNIA
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Attorneys for Plaintiffs
ADVANCED SURGICAL DESIGN and
MANUFACTURE LIMITED

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

Advanced Surgical Design and Manufacture Limited, an Australian company Plaintiff, vs. Portland Orthopaedics Pty. Ltd., an Australian company, and Portland Orthopaedics Incorporated, a Michigan corporation Defendants.	No. '08 CV 1117 WQH NLS COMPLAINT DEMAND FOR JURY TRIAL

The Parties

1. Advanced Surgical Design and Manufacture Limited, (ASDM), is an Australian company, having its principal place of business at Unit 2, 12 Frederick Street, St. Leonards, NSW, 2065, Australia ("Plaintiff" or "ASDM").

2. Upon information and belief, defendant Portland Orthopaedics Pty. Ltd. is

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an Australian corporation with its corporate offices and its principal place of business at Unit 3, 44 McCauley Street, Matraville, NSW, 2036, Australia, and defendant Portland Orthopaedics Incorporated, is a Michigan corporation authorized to do business and doing business in Michigan, with its corporate offices and its principal place of business at 1011 N. Riverside, St. Clair, MI, 48079 (hereinafter collectively, "Portland" or "Defendants").

Nature Of The Action

3. ASDM brings this action against Defendants to enjoin and redress Defendants' unauthorized and infringing uses of ASDM's United States Patent Nos. 6,712,857 ("the '857 patent") and 7,371,261 ("the '261 patent").

4. This action seeks injunctive relief, actual and exemplary monetary damages, attorneys' fees and costs based on Defendants' patent infringement under 35 U.S.C. § 271 *et. seq.*

Jurisdiction And Venue

5. Jurisdiction over the claims for patent infringement arising under the patent laws of the United States, including Title 35, is based on 28 U.S.C. §§ 1331 and 1338(a).

6. Venue is proper in this judicial district under 28 U.S.C §§ 1391 and 1400.

Background

7. United States Patent No. 6,712,857 ("the '857 patent), entitled ACETABULAR COMPONENT OF TOTAL HIP REPLACEMENT ASSEMBLY was duly and lawfully issued on March 30, 2004. ASDM is the current owner of all rights, title, and interest in the '857 patent. A true and correct copy of the '857 patent is attached hereto as Exhibit A.

8. United States Patent No. 7,371,261 ("the '261 patent), entitled ACETABULAR COMPONENT OF TOTAL HIP REPLACEMENT ASSEMBLY was duly and lawfully issued on May 13, 2008. ASDM is the current owner of all rights, title, and interest in the '261 patent. A true and correct copy of the '261 patent is attached hereto as Exhibit B.

9. ASDM is a developer, manufacturer, and marketer of innovative orthopedic products including hip and knee joint replacement products.

10. Upon information and belief, Defendant, Portland Orthopaedics Pty. Ltd. is an Australian based company that manufactures and markets hip and knee joint replacements. Defendant, Portland Orthopaedics Incorporated is the U.S. subsidiary of Defendant, Portland Orthopaedics Pty. Ltd.

11. Upon information and belief, Greg Roger, CEO and founder of Plaintiff ASDM, advised David Sekel, CEO of Portland, of the existence of the inventions disclosed in the '857 patent on or about June 11, 2003. The parties discussed ASDM making a hip cup for Portland. Greg Roger advised David Sekel to "stay clear" of the inventions disclosed in ASDM's '857 patent, which was shown to David Sekel. Thereafter, Portland ignored these warnings and deliberately copied the inventions disclosed in the '857 patent.

12. Upon information and belief, in January of 2007, Portland announced the launch of the Equator Plus Cup product in the United Sates. Upon information and belief, the first series of Equator Plus Cups where implanted in Portland, Oregon in January 2007 and the Equator Plus Cup product was exhibited at the Annual Meeting of the American Association of Orthopedic Surgeons in San Diego which took place between February 14 to 18, 2007. Upon information and belief, the "Equator Plus Cup is Portland's third product now available for sale in the U.S." [*See*, http://www.gbsventures.com.au/news_display_print.asp?NewsId=158]. ASDM became aware that Portland was offering for sale and introducing the Equator Plus Cup product shortly before the February 2007 association meeting in San Diego.

13. Counsel for ASDM sent cease and desist letters to the Defendants shortly before the San Diego meeting requesting that Defendants not introduce the Equator Plus Cup product and cease and desist from selling and offering for sale this product in the United States in view of the '857 patent. Thereafter, Defendants' Australian counsel and U.S. counsel responded and stated that Portland would not withdraw the Equator Plus Cup

product from the U.S. market.

14. Thereafter, ASDM obtained a second patent (the '261 patent) on May 13, 2008. The '261 patent also covers the Equator Plus Cup product. In 2008, ASDM initiated further discussions with Portland and attempted to resolve infringement concerns regarding the '857 and '261 patents. Those discussions have not proceeded in any meaningful way.

Patent Infringement

15. ASDM repeats and alleges each and every allegation contained in paragraphs 1 through 14 of this complaint as if fully set forth herein.

16. Upon information and belief, Defendants have infringed and are now infringing the '857 patent and the '261 patent by making, using, selling or offering to sell the claimed subject matter without the consent of ASDM.

17. Defendants' actions in the United States constitute direct infringement, inducement of infringement, contributory infringement, and/or willful infringement of the '857 patent and the '261 patent. Portland's Equator Plus Cup product infringes one or more claims of the '857 patent and the '261 patent under 35 U.S.C. § 271.

18. The Defendants' acts of infringement are causing substantial damage to ASDM and will continue to do so unless enjoined by this Court.

19. ASDM is informed and believes, and on that basis alleges that ASDM is entitled to recover damages in an amount to be proven at trial.

Prayer For Relief

WHEREFORE, ASDM prays that this Court enter a judgment in its favor and against Defendants:

A. Permanently enjoining Defendants, its shareholders, members, officers, directors, managers, employees, agents, attorneys, successors and assigns, and all persons in active concert or participation with them or any of them, from manufacturing, selling, offering for sale or distributing the Equator Plus Cup product or any other product that infringes ASDM's patents.

B. Declaring that Defendants have directly infringed, induced the infringement of, contributorily infringed, and/or willfully infringed the patents in suit.

C. Declaring that Defendants have copied ASDM's claimed inventions.

D. Ordering Defendants to pay treble damages for Defendants' willful infringement of ASDM's property rights.

E. Ordering destruction of all of the Defendants' infringing product and any components thereof, as well as any promotional materials, printed packages, brochures, advertisements, documents or things that refer to Defendants' infringing product.

F. Ordering Defendants to pay damages that ASDM has sustained as a consequence of Defendants' infringement of ASDM's patents and interest thereon caused by Defendants' infringement, pursuant to 35 U.S.C. § 284, and/or any other appropriate monetary relief.

G. Ordering that ASDM have and recover its reasonable attorneys' fees, filing fees and reasonable costs of suit incurred in this litigation.

H. Ordering that ASDM have such other and further relief as the nature of the case may require and as this Court may deem just and proper under the circumstances.

Date: June 23, 2008

Respectfully submitted,

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Attorneys for Plaintiff, ASDM

Demand for Jury Trial

ASDM demands a trial by jury for each matter so triable as of right. Rule 38, Federal Rules of Civil Procedure.

Dated: June 23, 2008

Respectfully submitted,

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EXHIBITS

TABLE OF CONTENTS

US006712857B1

(12) **United States Patent**
Roger

(10) **Patent No.: US 6,712,857 B1**
(45) **Date of Patent: Mar. 30, 2004**

(54) **ACETABULAR COMPONENT OF TOTAL HIP REPLACEMENT ASSEMBLY**

(75) Inventor: **Gregory James Roger**, New South Wales (AU)

(73) Assignee: **Australian Surgical Design and Manufacture Pty Limited**, Miranda (AU)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 53 days.

(21) Appl. No.: **09/926,684**

(22) PCT Filed: **May 31, 2000**

(86) PCT No.: **PCT/AU00/00619**

§ 371 (c)(1),
(2), (4) Date: **Mar. 4, 2002**

(87) PCT Pub. No.: **WO00/74604**

PCT Pub. Date: **Dec. 14, 2000**

(30) **Foreign Application Priority Data**

Jun. 2, 1999 (AU) ..... PQ 0703

(51) **Int. Cl.**[7] **A61F 2/34**; A61F 2/46
(52) **U.S. Cl.** **623/22.21**; 623/22.39
(58) **Field of Search** 623/22.11, 22.15, 623/22.21, 22.22, 22.23, 22.24, 22.39

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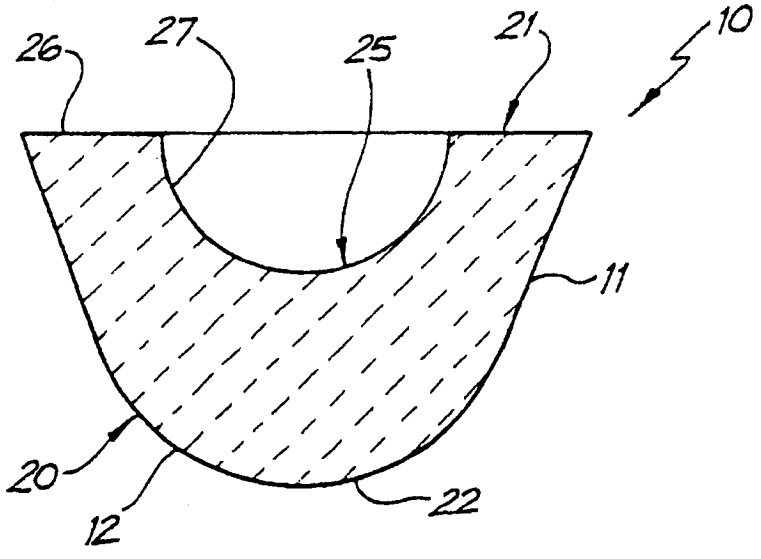
Primary Examiner—Ralph A. Lewis
(74) *Attorney, Agent, or Firm*—Jacobson Holman PLLC

(57) **ABSTRACT**

A device for use in surgical procedures involving arthroplasty. The device includes a socket member having a first surface and a second bone engaging surface. The first surface has a bearing surface adapted to receive a counter-component of a joint such as the head of a femur (or prosthesis thereof). The bone engaging surface includes a first, preferably frusto-conical, portion and a second portion preferably including a spherical section.

15 Claims, 3 Drawing Sheets



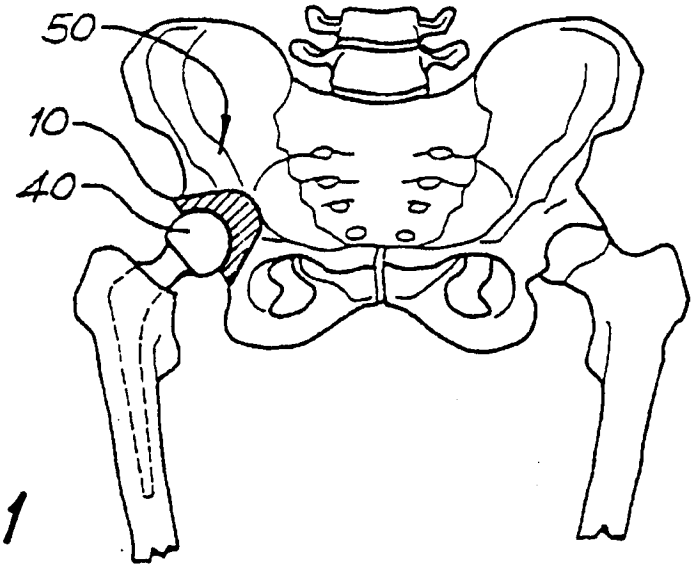


FIG. 1

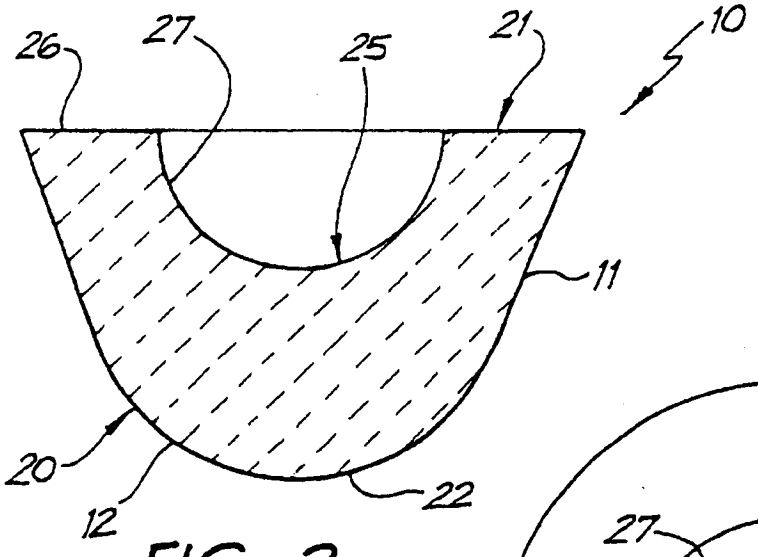


FIG. 2a

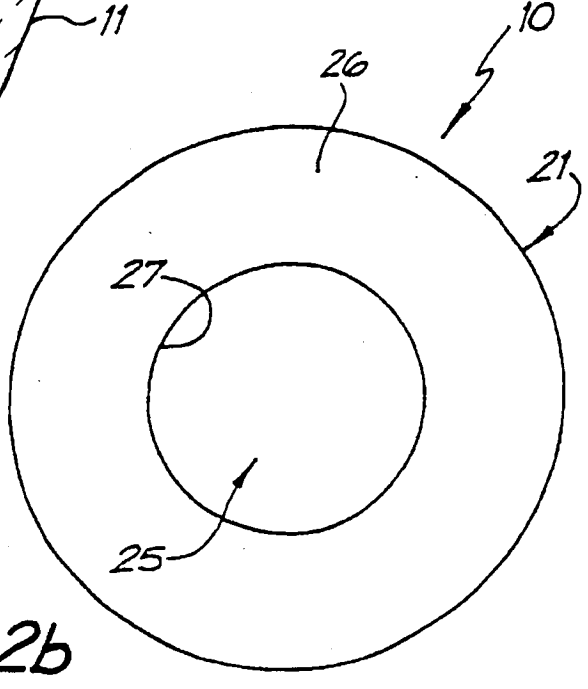


FIG. 2b

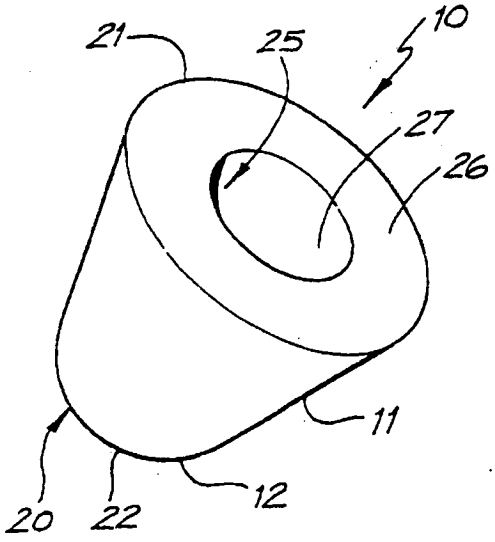


FIG. 3a

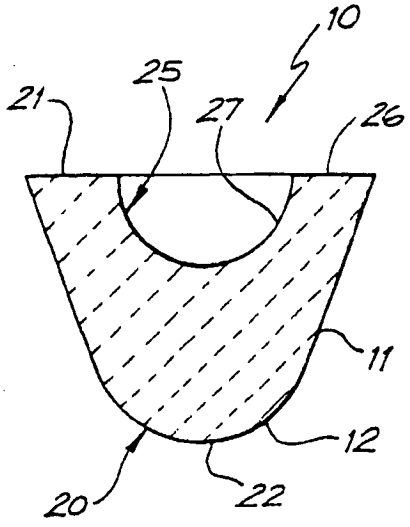


FIG. 3b

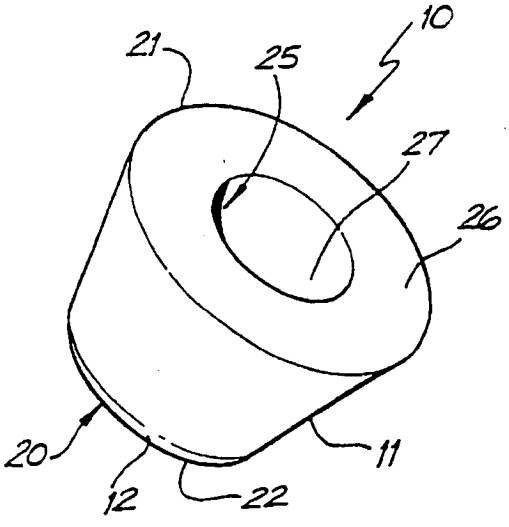


FIG. 4a

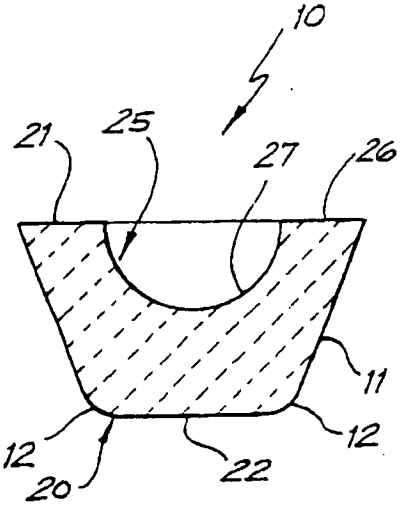


FIG. 4b

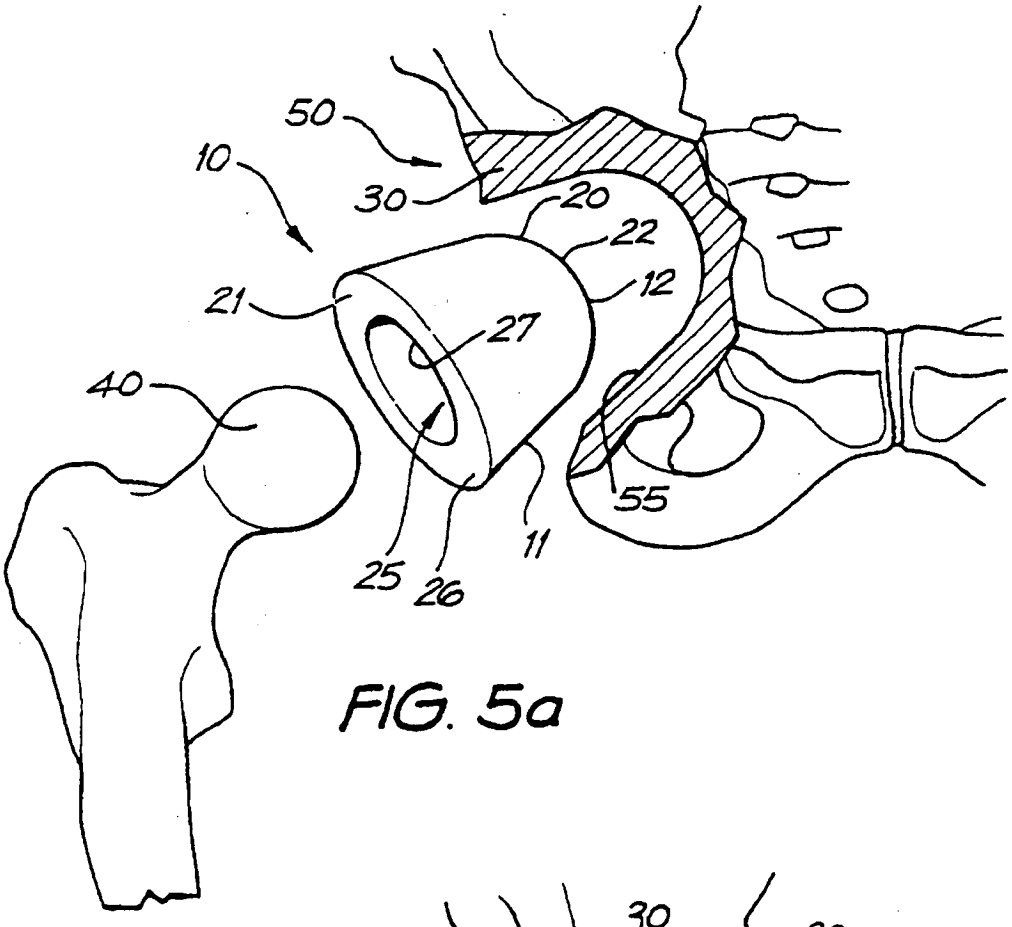

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FIG. 5a

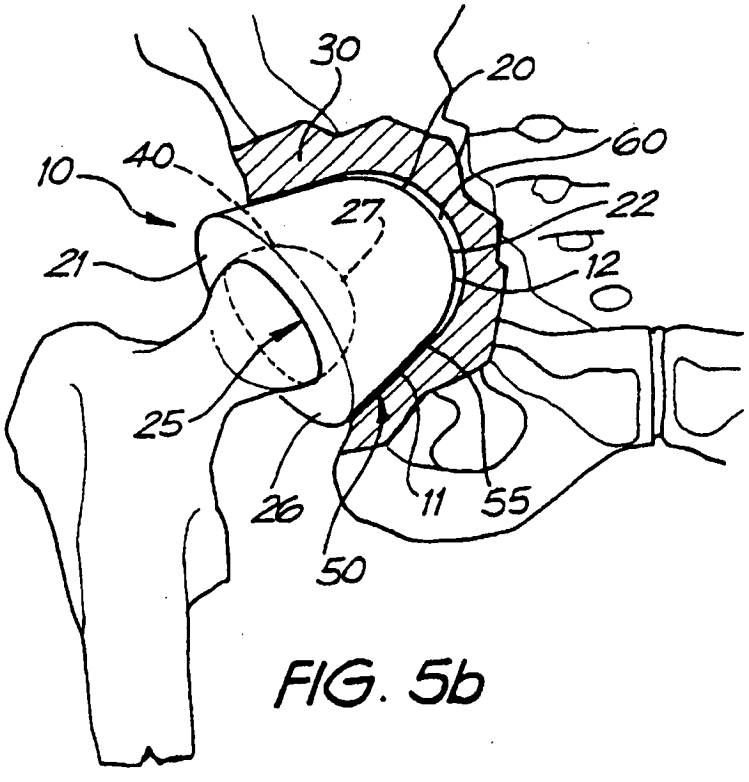
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FIG. 5b

ACETABULAR COMPONENT OF TOTAL HIP REPLACEMENT ASSEMBLY

FIELD OF THE INVENTION

The present invention generally relates to a method and apparatus for use in surgical procedures involving arthroplasty. More specifically, it relates to a prosthetic socket portion of a joint replacement assembly, and a method for its insertion during arthroplasty. Particular reference is drawn to the apparatus in the form of an acetabular portion of a total hip replacement assembly.

BACKGROUND ART

The inclusion of the following description of the prior art is not an admission that the prior art is part of the common general knowledge in Australia.

It is well known to use prosthetic joint replacements in patients with various kinds of disorders affecting the joints, including degenerative disorders, such as severe osteoarthritis.

Over the years, a vast array of materials have been developed and utilised in the construction and manufacture of such prostheses. This is partly because the knowledge base regarding materials, and relevantly biocompatible materials, has been growing. It is also because, despite technological advances, there are a continuing number of complications associated with joint replacement prostheses with which surgeons and patients must grapple. As a result, surgeons and other inventors in the field have had, and are still challenged with, an ongoing quest to improve on the ease of insertion of the prostheses, to reduce the incidence of long and short term complications associated with using them, and to improve on the longevity of both the bio-prosthetic interface, and the prostheses themselves.

Since the present invention refers specifically to a socket portion of a joint replacement assembly, and particularly refers to an acetabular component of a total hip replacement assembly, it is the latter which the following discussion briefly addresses.

The hip joint is comprised of the head of the femur articulating with the acetabulum. The acetabulum is generally cotyloidal in shape, and is often referred to as a "cup".

One of the first designs for the acetabular component of the hip joint, which was developed around 1960, was a hemisphere of metal internally lined with a plastics hemisphere, with the latter acting as the articulation surface. The metal was cemented into the bone and the liner was either pressed into the metal cup during the arthroplasty procedure, or was incorporated into the prosthesis during manufacture. In some later designs, the preferred method of securing the prosthesis was to screw it to the bone. However, while providing good fixation, screws have been found to lead to serious complications in the hip and are now not well regarded. Consequently, some of the more recent developments in acetabular prostheses have focused oil new designs for their bone contacting surfaces. For example, some acetabular prostheses have been manufactured with a self-cutting thread on their bone contacting surface, while others have relied on press fitting along with cement, or a combination of surface roughening and hydroxyapatite.

In addition to considerable variation in the designs of the outer, or bone contacting, surfaces of acetabular prostheses, however, much research has been done in order to provide improved means of engaging the head of the femur (or prosthesis thereof). Forte (U.S. Pat. No. 5,062,853), for example, describes a particular construction for the inner aspect of the acetabular prosthesis which is particularly well adapted to receive and engage a corresponding prosthetic head of a femur.

Nevertheless, while prosthetic hip joint replacements have been shown to be incredibly beneficial for patients who require them, there are still a number of problems associated with their insertion for which further developments in the method and apparatus would be advantageous. The present invention is, most specifically, aimed at improving the bone contacting surface of acetabular prostheses, and therefore addresses many of the problems raised above.

DESCRIPTION OF THE INVENTION

In a first aspect, the present invention consists in a device for use in surgical procedures involving arthroplasty, the device including a socket member having a first surface and a second bone engaging surface, the first surface including at least a bearing surface adapted to receive a counter-component of a joint, and the bone engaging surface including a first portion having a shape, and at least a second portion having a different shape to that of the first portion.

In a second aspect, the present invention consists in a method of inserting a device according to the first aspect during an arthroplasty procedure, the method including the steps of:

a) bringing a surface of an appropriate joint orientation determining means into apposition with the exposed surface of the socket portion of a joint;

b) manipulating the joint orientation determining means so that the correct angular orientation for a socket portion of a joint replacement assembly is determined;

c) forming a hole into the bone adjacent the joint orientation determining means with a hole forming means, using said joint orientation determining means as a guide;

d) removing the joint orientation determining means from apposition with said exposed surface:

e) using the hole formed in step (c) as a guide, reaming an appropriately shaped and sized portion of bone from the bone forming the socket portion of the joint to a desired depth, thereby creating a reamed surface of bone;

f) bringing the bone engaging surface of a device according to the first aspect of the invention into contact with the reamed surface of bone; and

g) securing the device to the bone.

The device according to this invention may be used in a range of arthroplasty procedures, but is of particular applicability when used as a replacement for the acetabular component of a hip joint. By virtue of the nature of its function, preferred embodiments disclose that the socket member, as a whole, has a cotyloidal configuration with a longitudinal axis. The first surface of the socket member includes a bearing surface having a radius of curvature which is adapted to receive the counter-component of a joint, such as the head of the femur (or prosthesis thereof) in a hip joint. The socket member is, according to this invention, defined by a bone engaging surface. In accordance with its name, the bone engaging surface is adapted to engage a bony surface comprising a portion of the joint which the device is intended to replace, such as the acetabulum in a hip joint.

Preferred embodiments of the invention disclose that the bone engaging surface of the socket member comprises at

least a first and a second portion. In such embodiments, the first portion extends away from a circumferential join with the first surface of the socket member, and the second portion extends away from a circumferential join with the first portion to an extremity.

In further preferred embodiments, as the first portion extends away from its join with the first surface of the socket member, its cross-sectional diameter may decrease at a first rate. In such embodiments, the rate of change in cross-sectional diameter may be linear such that the first portion has a frusto-conical shape. In alternative embodiments, the rate of change may be logarithmic, exponential or may follow any other mathematical expression. In yet further alternative embodiments, the rate of change may itself change from one to another of these mathematical expressions as the first portion extends away from its join with the first surface.

Similarly, as the second portion extends away from its join with the first portion, its cross-sectional diameter may decrease at a second different rate to that of the cross-sectional diameter of the first portion. In preferred embodiments, the rate of change will comply with a mathematical expression which will cause the second portion to form a spherical section, and preferably, a hemi-section or a smaller section still. In alternative embodiments, the discussion of the mathematical expressions according to which the rate of change may comply from the paragraph above is also applicable to the rate of change for the cross-sectional diameter of the second portion.

As indicated above, however, in a preferred embodiment the first portion of the bone engaging surface is frusto-conical, while the second portion comprises a spherical section. Construction of the device according to either of these aspects of the invention, therefore, envisages the bone engaging surface of the socket member including any one of a plurality of combinations of portions having these, and other additional, shapes.

In some such embodiments of the invention, for example, the bone engaging surface includes a plurality of portions of different shapes, wherein at least one portion is frusto-conical, and another, comprises a spherical section, while in other embodiments, the bone engaging surface includes only two portions, each having one of the latter shapes. Indeed, embodiments of the invention wherein these two portions alone comprise the bone engaging surface are preferred. Consequently, the foregoing description outlines preferred structural combinations of the frusto-conical portion and portion comprising a spherical section for the bone engaging surface of the socket member.

In preferred embodiments, the bone engaging surface of the socket member is substantially hemispherical, having its rounded extremity formed by the portion of the bone engaging surface comprising a spherical section. In other words, in these particular embodiments, the frusto-conical portion of the bone engaging surface is oriented so that its smallest cross-sectional diameter meets, circumferentially, with the hemisphere formed by the portion comprising a spherical section; and its largest cross-sectional diameter meets, circumferentially, with the first surface of the socket member.

In alternative embodiments, the bone engaging surface comprises a frusto-conical portion, a portion comprising a spherical section, and a planar portion or a portion comprising a section of a larger sphere than the latter. Such embodiments disclose a similar configuration to that described in the preceding paragraphs. However, while the extremity of the bone engaging surface still has a substantially hemispherical surface, a portion of that surface is essentially planar.

As indicated earlier, the scope of this invention is not limited to the embodiments just described. There are multiple variations for the construction of the bone engaging surface having a plurality of portions, each with unique shapes, which fall within its scope. However, it is noteworthy that the incorporation of a bone engaging surface having a combination of a frusto-conical portion and portion comprising a spherical section may contribute considerably to the functionality and securability of the socket member.

In replacing a socket portion of a joint, the fixation of the socket member must be able to withstand rotational and other movement influencing forces created during articulation of the joint. While the means used to secure the socket member to the bone (see below) will be of substantial importance in this regard, having a frusto-conical shape for a portion of the bone engaging surface of the invention is also of particular value, as such a shape has excellent side rotational stabilising capacity.

In addition, such a shape helps to ensure that any compressive forces which the socket member applies to the bone during, for example, weight-bearing, is desirably distributed: with a frusto-conical shape, compression of the bone will be greatest at the largest cross-sectional diameter of the frusto-conical portion, namely, around the first surface of the socket member. The latter will, when the socket member has been inserted according to this invention, be located near the surface of the bone. It is desirable for the greatest compressive force which the socket member applies to the bone to be distributed at this location. This is because, if the greatest compression occurs in deeper regions of the bone, for example, those regions adjacent the extremity of the bone engaging surface of the socket member, then the surface bone is protected from stress and tends to weaken.

The capacity of a socket member according to this invention to distribute such compressive forces desirably is further augmented by the presence of a portion comprising a spherical section near or at the extremity of the bone engaging surface. In preferred embodiments, the bone engaging surface of the socket member, despite being comprised of a plurality of portions each having unique shapes, is continuous, in that the meeting loci of these portions are not interrupted, or constructed, by a sharp edge or a 'step'. When the portion comprising a spherical section is at the extremity of the bone engaging surface it acts as a further means to ensure that no such edge or step is in contact with the surrounding bone. The value of ensuring as much, especially near the extremity of the bone engaging surface, is that an edge-like or step-like protrusion would, during the application of weight-bearing compressive forces, act as a stress riser on the bone. For the reasons already outlined, among others, this is not desirable.

Preferred embodiments also disclose that a bearing surface is located at the first surface of the socket member. Such a bearing surface, has the capacity to receive the counter-component of a joint such as the head of the femur (or prosthesis thereof) in a hip joint.

In some such embodiments of the invention, the first surface of the socket member is comprised of a relatively planar surface into which the bearing surface forms an indent. Because the bearing surface receives the counter-component of the joint, the materials used in the construction of the invention warrant discussion: while there are no particular limitations on the materials to be used in the manufacture of the socket member, it is replacing a bony component of a joint, and must, therefore, have similar characteristics in terms of strength and resilience. Various metals, as well as ceramics, or carbon fibre may all be

appropriate. As an integral component of the socket member, the bearing surface will also be made of such a material. However, since this surface of the socket member represents the articulating surface of the joint, it is desirable to use a high-wear resistance material such as polyethylene or ceramics. Accordingly, in preferred embodiments of the invention, a shell being made of polyethylene, or similar appropriate material, and having a shape which corresponds with the bearing surface is machine fitted to the latter. Note, however, that although machine fitting provides for a tighter fit and a convenient form of manufacture, it is not a requisite component of this invention that the shell be fitted by machine. Indeed, any appropriate method of fitting the shell, including for example, by known methods of clipping it into position, falls within the scope of this invention.

It is further noteworthy that as the bearing surface comes under load, there may be relative movement, or micro-motion, between the shell and the bearing surface of the socket member to which it is fitted. This can generate wear particles. In order to render less likely such generation, preferred embodiments of the invention disclose that an interface between the bearing surface of the socket member and the shell is surface-coated with a material, such as titanium nitrate or titanium carbide.

Additionally disclosed is a method for inserting a socket member according to the invention during an arthroplasty procedure. Although not required in many cases, it may initially be necessary for the surgeon to perform a small hemispherical ream into the bone forming the socket portion of the joint. It may be appropriate to do so in cases where this part of the joint has undergone severe pathological degeneration. Nevertheless, whether or not the decision is made to perform the small hemispherical ream, the method generally includes the steps of:

a) bringing a surface of an appropriate joint orientation determining means into apposition with the exposed surface of the socket portion of the joint. For the purposes of this disclosure, a "joint orientation determining means" refers to an appropriate device which can be used to determine the correct orientation for a replacement prosthesis;

b) manipulating the joint orientation determining means so that the correct angular orientation for a socket portion of a joint replacement assembly is determined. Such determination is critical, both for ensuring the best alignment and also for finding a position which provides the least likelihood of dislocation. Determination of the correct angular orientation may be achieved by having reference to appropriate anatomical landmarks, by simple visualisation, or with whatever method is preferred by the surgeon;

c) forming a hole into the bone adjacent the joint orientation determining means with a hole forming means, such as a drill bit, using said joint orientation determining means as a guide. In preferred embodiments of the invention, the joint orientation determining means is pre-prepared with a hole designed to receive the hole forming means. In alternative embodiments, it may not be;

d) removing the joint orientation determining leans from apposition with the exposed surface of bone;

e) using the hole formed in (c) as a guide, reaming an appropriately shaped and sized portion of bone from the bone forming the socket portion of the joint to a desired depth, thereby creating a reamed surface of bone. In preferred embodiments, the reamed surface should extend to a depth slightly beyond the depth attained, according to this invention, by the extremity of the bone engaging surface of a fully inserted socket member.

f) bringing the bone engaging surface of a socket member according to the invention into contact with the reamed surface of bone; and

g) securing the socket member to the bone. In preferred embodiments, the socket member is press fit, and not threaded. While a socket member having a thread is not outside the scope of this invention, the press fit solution is preferred as it significantly decreases the technical complexity of insertion. As explained in (e) above, when the socket member is fully inserted, preferred embodiments disclose that there should be a small space between the extremity of the bone engaging surface and the reamed surface of bone. This space provides room to allow for a small amount of subsidence of the socket member when it is subjected to compressive forces, for example, during weight-bearing.

Reinforced fixation of the socket member in the correct position may additionally be achieved by cement, by a combination of roughening and hydroxyapatite, or by any other appropriate means.

The socket member, according to this invention, is now ready to receive the counter-component of the joint, or a prosthesis thereof.

More specifically, in cases where a socket member according to the invention will be used to replace the acetabular portion of a hip joint, similar commentary regarding the steps above is appropriate, but in summary, the method includes the following:

a) bringing a convex surface of a hemispherical cup (an appropriate joint determining means for hip joint arthroplasty) into apposition with the exposed surface of the acetabulum;

b) manipulating the hemispherical cup so that the correct angular orientation for an acetabular portion of a total hip replacement assembly is determined;

c) forming a hole into the bone adjacent the hemispherical with a hole forming means, such as a drill bit, using said hemispherical cup as a guide;

d) removing the hemispherical cup from apposition with the exposed surface of the acetabulum;

e) using the hole drilled in (c) as a guide, reaming an appropriately sized frusto-conical portion of bone from the acetabulum to a desired depth, thereby creating a reamed surface of bone;

f) bringing a socket member according to this invention into contact with the reamed surface of bone; and

g) securing the socket member to the bone.

The socket member is now ready to receive the head of the femur, or a prosthesis thereof.

In accordance with this latter description, pertaining to a method for inserting a device according to the invention in an arthroplasty procedure on the hip joint, a further aspect to the invention is disclosed:

In a third aspect, the present invention consists in a method of inserting a device according to the first aspect during an arthroplasty procedure involving the hip joint, wherein the bone engaging surface is comprised of a first frusto-conical portion and at least a second portion, wherein the second portion includes a spherical section, the method including the steps of:

a) bringing a convex surface of a hemispherical cup into apposition with the exposed surface of the acetabulum;

b) manipulating the hemispherical cup so that the correct angular orientation for an acetabular portion of a hip replacement assembly is determined;

c) forming a hole in the acetabulum with a hole forming means, using the hemispherical cup as a guide;

d) removing the hemispherical cup from apposition with said exposed surface of acetabulum;

e) using the hole drilled in (c) as a guide, reaming an appropriately sized frusto-conical portion of bone from the acetabulum to a desired depth, thereby creating a reamed surface of bone;

f) bringing a device according to this aspect of the invention into contact with the reamed surface of bone; and

g) securing the device to the bone.

A significant advantage of the present invention is that in the event that an error is made while carrying out step (e), and the ream is found to be in the wrong direction, the option is still available to then use a hemispherical reamer to slightly enlarge the reamed surface of bone, with minimal extra bone resection. In this instance, it will be possible to still position a hemispherical socket member against the reamed hemispherical surface and secure it to the bone. Thus, the present invention additionally offers a satisfactory avenue for dealing with initial errors of alignment in reaming the appropriately sized frusto-conical portion of bone.

BRIEF DESCRIPTION OF THE DRAWINGS

By way of example, preferred embodiments of the invention are described with reference to the accompanying drawings in which:

FIG. **1** is a schematic representation of a prosthetic total hip replacement assembly, as inserted, following arthroplasty to the right hip;

FIG. **2***a* is a cross-sectional view of a socket member according to a preferred embodiment of the invention;

FIG. **2***b* is a diagrammatic representation of a top view of the socket member in FIG. **2***a*, illustrating the first surface of that socket member;

FIG. **3***a* is a perspective view of a socket member according to the preferred embodiment of the invention illustrated in FIG. **2***a*;

FIG. **3***b* is a cross-sectional view of the socket member of FIG. **3***a*;

FIG. **4***a* is a perspective view of a socket member according to another embodiment of this invention;

FIG. **4***b* is a cross-sectional view of the socket member of FIG. **4***a*;

FIG. **5***a* is an exploded perspective view illustrating the relative positions of the reamed surface of the acetabulum, the socket member according to a preferred embodiment of the invention, and the head of the femur (or prosthesis thereof), as they are each about to be inserted into the right hip; and

FIG. **5***b* is a perspective view illustrating the componentry shown in FIG. **5***a* as correctly inserted into the right hip.

PREFERRED MODE OF CARRYING OUT THE INVENTION

The device according to this invention may be used in a range of arthroplasty procedures, but is of particular applicability to arthroplasty procedures involving the hip joint (see FIG. **1**).

The socket member **10** has a bone engaging or contacting surface **20** that is comprised of a first portion which is frusto-conical **11**, and a second portion comprising a spherical section **12**. Consequently, the foregoing description outlines preferred structural combinations of the frusto-conical portion **11** and portion comprising a spherical section **12** for the bone contacting surface **20** of the socket member **10**.

The bone contacting surface **20** of the socket member **10** extends away from the socket member's first surface **21** in such a way that the cross-sectional diameter of the bone contacting surface **20** (in a plane substantially perpendicular to the longitudinal axis) diminishes at one rate for the frusto-conical portion **11**, and diminishes at a second different rate for the second portion comprising a spherical section **12** to a rounded extremity **22**. In other words, the frusto-conical portion **11** of the bone contacting surface **20** is oriented so that its smallest cross-sectional diameter meets, circumferentially, with the hemispherical section formed by the portion comprising a spherical section **12**; and its largest cross-sectional diameter meets, circumferentially, with the first surface **21** of the socket member **10**.

As indicated earlier, the scope of this invention is not limited to the embodiments just described. There are multiple variations for the construction of the bone contacting surface **20** having a plurality of portions, each with unique shapes, which fall within its scope. However, as noted in the description of the invention the incorporation of a bone contacting surface **20** having a combination of a frusto-conical portion **11** and portion comprising a spherical section **12** may contribute considerably to the functionality and securability of the socket member **10**.

In replacing a socket portion of a joint, the fixation of the socket member **10** must be able to withstand rotational and other movement forces created during articulation of the joint. Having a frusto-conical shape for a portion **11** of the bone contacting surface **20** of the invention is also of particular value, as such a shape has excellent side rotational stabilising capacity.

In addition, such a shape helps to ensure that any compressive forces which the socket member **10** applies to the bone during, for example, weight-bearing, is desirably distributed: with a frusto-conical shape **11**, compression of the bone will be greatest at the largest cross-sectional diameter of the frusto-conical portion **11**, namely, at around the join with the first surface **21** of the socket member **10**. The latter will, when the socket member **10** has been inserted according to this invention, be located near the surface of the bone **30**. It is desirable for the greatest compressive force which the socket member **10** applies to the bone **30** to be distributed at this location. This is because, if the greatest compression occurs in deeper regions of the bone **30**, for example, those regions adjacent the extremity **22** of the bone contacting surface **20** of the socket member **10**, then the surface bone **30** is protected from stress and tends to weaken.

The capacity of a socket member **10** according to this invention to distribute such compressive forces desirably is further augmented by the presence of a portion comprising a spherical section **12** near or at the extremity **22** of the bone contacting surface **20**. In preferred embodiments, the bone contacting surface **20** of the socket member **10**, despite being comprised of two portions each having unique shapes (**11** and **12** respectively), is continuous, in that the meeting loci of these portions **11** and **12** are not interrupted, or constructed, by a sharp edge or a 'step'. When the portion comprising a spherical section **12** is at the extremity **22** of the bone contacting surface **20** it acts as a further means to

ensure that no such edge or step is in contact with the surrounding bone **30**. The value of ensuring as much, especially near the extremity **22** of the bone contacting surface **20**, is that an edge-like or step-like protrusion would, during the application of weight-bearing compressive forces, act as a stress riser on the bone. For the reasons already outlined, among others, this is not desirable.

The bearing surface **25** is located at the first surface **21** of the socket member **10**. Such a bearing surface **25**, has the capacity to receive the counter-component of a joint such as the head of the femur **40** (or prosthesis thereof) in a hip joint. In fact, the first surface **21** of the of the socket member **10** is comprised of a relatively planar annular surface **26** into which the bearing surface **25** forms an indent.

While there are no particular limitations on the materials to be used in the manufacture of the socket member **10**, it is replacing a bony component of a joint, and must, therefore, have similar characteristics in terms of strength and resilience. As already explained, various metals, as well as ceramics, or carbon fibre may all be appropriate. As an integral component of the socket member **10**, the bearing surface **25** will also be made of such a material. However, since this surface **25** of the socket member **10** represents the articulating surface of the joint, it is desirable to use a material of high wear resistance such as polyethylene or ceramics. Accordingly, a shell **27** being made of polyethylene, or similar appropriate material, and having a shape which corresponds with the bearing surface **25** is, in the depicted embodiment, machine fitted to the latter. However, although machine fitting provides for a tighter fit and a convenient form of manufacture, it is not a requisite component of this invention that the shell **27** be fitted by machine. Indeed, any appropriate method of fitting the shell **27**, including for example, by known methods of clipping it into position, falls within the scope of this invention.

In addition, as the bearing surface **25** comes under load, there may be relative movement, or micro-motion, between the shell **27** and the bearing surface **25** of the socket member **10** to which it is fitted. This can generate wear particles. In order to render less likely such generation, the interface between the bearing surface **25** of the socket member **10** and the shell **27** is surface-coated with a material, such as titanium nitrate or titanium carbide.

Also disclosed is a method for inserting a socket member **10** according to the invention as a prosthetic replacement for the acetabular portion of a hip joint (see FIG. **1**). Although not required in many cases, it may initially be necessary for the surgeon to perform a small hemispherical ream into the acetabulum **50**. It may be appropriate to do so in cases where this part of the joint has undergone severe pathological degeneration. Nevertheless, whether or not the decision is made to perform the small hemispherical ream, the method generally includes the steps of:

a) bringing a convex surface of a hemispherical cup (not shown) (an appropriate joint determining means for hip joint arthroplasty) into apposition with the exposed surface of the acetabulum **50**;

b) manipulating the hemispherical cup (not shown) so that the correct angular orientation for an acetabular portion of a total hip replacement assembly is determined. Such determination is critical, both for ensuring the best alignment and also for finding a position which provides the least likelihood of dislocation. Determination of the correct angular orientation may be achieved by having reference to appropriate anatomical landmarks, by simple visualisation, or with whatever method is preferred by the surgeon;

c) forming a hole (not shown) into the bone **30** adjacent the hemispherical cup (not shown) with a drill bit (not shown), using said hemispherical cup as a guide. The hemispherical cup is normally pre-prepared with a hole designed to receive the drill bit;

d) removing the hemispherical cup (not shown) from apposition with the exposed surface of the acetabulum **50**;

e) using the hole drilled in (c) as a guide, reaming an appropriately sized frusto-conical portion of bone from the acetabulum to a desired depth, thereby creating a reamed surface **55** of bone **30**. The reamed surface **55** should extend to a depth slightly beyond the depth attained, according to this invention, by the extremity **22** of the bone contacting surface **20** of a fully inserted socket member **10**.

f) bringing a socket member **10** according to this invention into contact with the reamed surface **55** of bone **30**; and

g) securing the socket member **10** to the bone **30**. In the depicted embodiment, the socket member **10** is press fit, and not threaded. As explained in (e) above, when the socket member **10** is fully inserted, there should be a small space **60** between the extremity **22** of the bone contacting surface **20** and the reamed surface **55** of bone **30**. This space **60** provides room to allow for a small amount of subsidence of the socket member **10** when it is subjected to compressive forces, for example, during weight-bearing.

Reinforced fixation of the socket member **10** in the correct position may additionally be achieved by cement, by a combination of roughening and hydroxyapatite, or by any other appropriate means.

The socket member **10**, according to this invention, is now ready to receive the head of the femur **40**, or a prosthesis thereof.

It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the invention as shown in the specific embodiments without departing from the spirit or scope of the invention as broadly described. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive.

What is claimed is:

1. A device for use in surgical procedures involving arthroplasty, the device comprising

a socket member having a first surface that includes at least a bearing surface adapted to receive a counter component of a joint, and

a bone engaging surface, the bone engaging surface having

a first surface portion that extends away from a circumferential join with the first surface, a cross-sectional diameter of the first surface portion decreasing at a first rate as the first surface portion extends away from the circumferential join with the first surface, and

at least a second surface portion that extends away from a the first surface portion to an extremity, a cross-sectional diameter of the second surface portion decreasing at a second rate,

the second rate being different from the first rate,

whereby the first surface portion and the second surface portion are arranged relative to each other such that the bone engaging surface is devoid of a step or a corner.

2. The device of claim **1** wherein the bone engaging surface being devoid of a step or a corner prevents the application of undue stress to the surrounding bone.

3. The device of claim 1 when used as a replacement for the acetabular component of a hip joint.

4. The device of claim 1 wherein the first rate of decrease in cross-sectional diameter of the socket member is linear.

5. The device of claim 1 wherein the second rate of decrease in cross-sectional diameter of the socket member is logarithmic or exponential.

6. The device of claim 1 wherein, the second rate of decrease in cross-sectional diameter of the socket member varies as the second surface portion extends away from a line of meeting with the first surface portion and the second surface portion.

7. The device of claim 1 wherein the first surface portion is defined by a frustoconical section of the socket member and the second surface portion is defined by a spherical section of the socket member.

8. The device of claim 7 wherein the frusto-conical section of he socket member is oriented so that its smallest cross-sectional diameter meets, circumferentially, with a hemisphere formed by the spherical section and its largest cross-sectional diameter meets, circumferentially, with the first surface of the socket member.

9. The device of claim 1 wherein the socket member is cotyloidal in configuration with a longitudinal axis.

10. The device of claim 1 wherein the first surface of the socket member comprises a relatively planar surface into which the bearing surface forms an indent.

11. The device of claim 1 wherein the socket member is made from any one of the group comprising metals, ceramics, or carbon fibre.

12. The device of claim 1 wherein the bearing surface of the socket member is made from a material of higher wear resistance relative the remaining material of the socket member.

13. The device of claim 12 wherein the bearing surface is made from polyethylene or a ceramic material.

14. The device of claim 1 wherein a shell of polyethylene having a shape which corresponds with the bearing surface is fitted to the bearing surface.

15. The device of claim 14 wherein an interface formed between the bearing surface of the socket member and the shell is surface-coated with titanium nitrate or titanium carbide.

* * * * *

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(12) United States Patent
Roger

(10) Patent No.: US 7,371,261 B2
(45) Date of Patent: *May 13, 2008

(54) **ACETABULAR COMPONENT OF TOTAL HIP REPLACEMENT ASSEMBLY**

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(73) Assignee: **Advanced Surgical Design & Manufacture Ltd.**, St. Leonards, New South Wales (AU)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 375 days.

This patent is subject to a terminal disclaimer.

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(51) **Int. Cl.**
A61F 2/32 (2006.01)

(52) **U.S. Cl.** **623/22.21**; 623/22.39

(58) **Field of Classification Search** 623/22.21, 623/22.24, 22.25, 22.26, 22.28
See application file for complete search history.

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Primary Examiner—Ralph A. Lewis
(74) *Attorney, Agent, or Firm*—Jones Day

(57) **ABSTRACT**

A device for use in surgical procedures involving arthroplasty, the device including a bearing member at least partially receivable within a bone engaging member and a liner positioned at least partially between said bearing member and said bone engaging member.

31 Claims, 5 Drawing Sheets

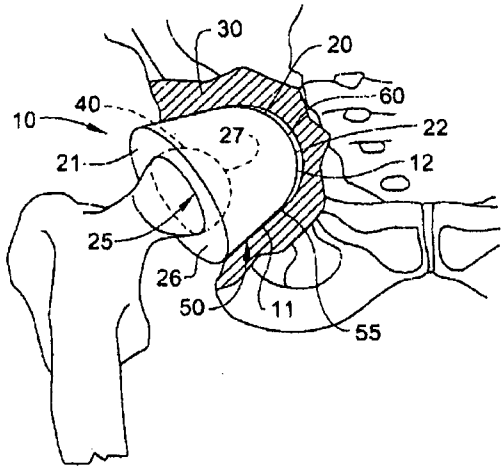

FIG. 1

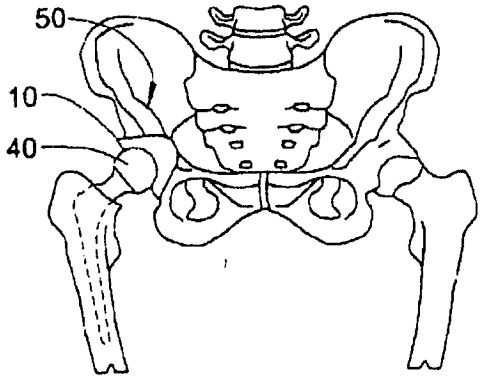

FIG. 2a

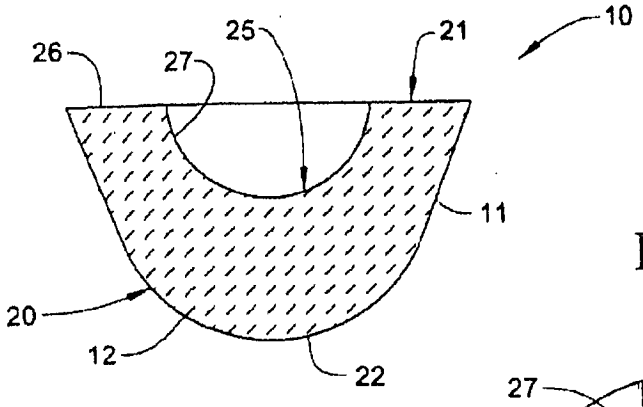

FIG. 2b

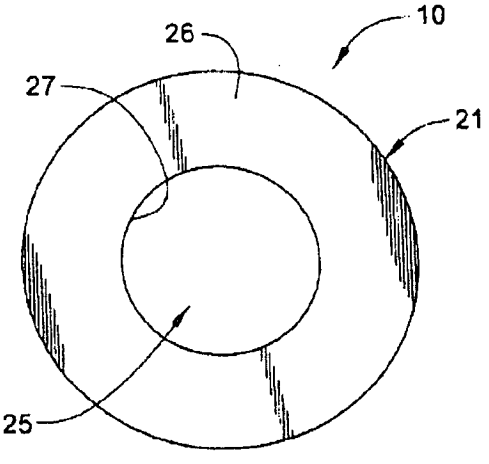

FIG. 3a

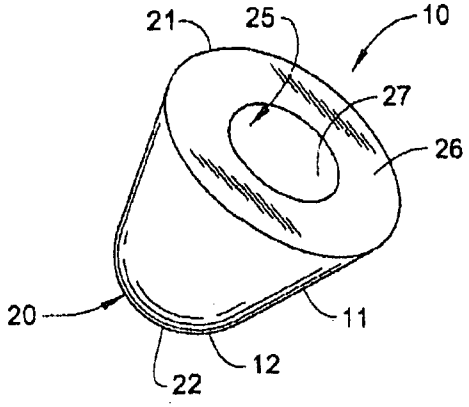

FIG. 3b

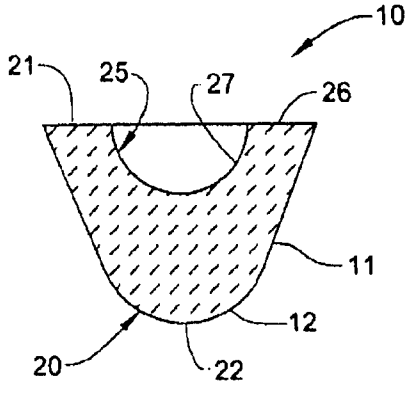

FIG. 4a

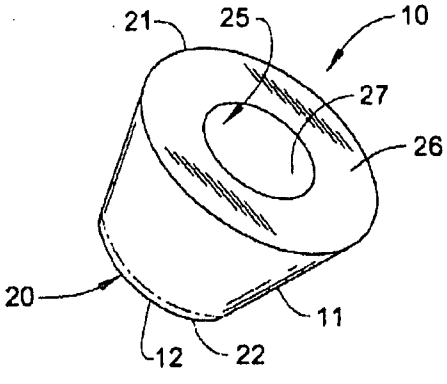

FIG. 4b

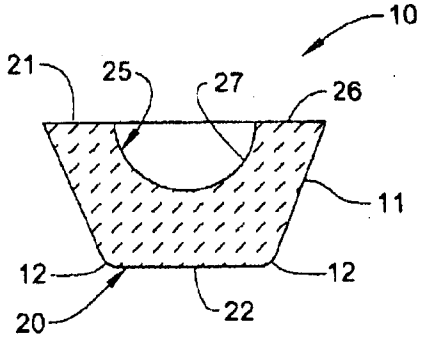

FIG. 5a

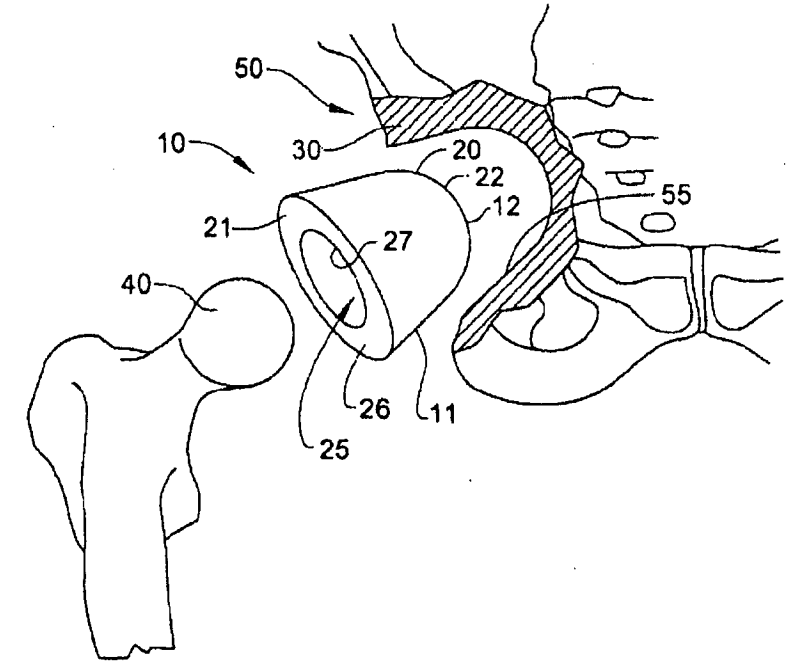
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FIG. 5b

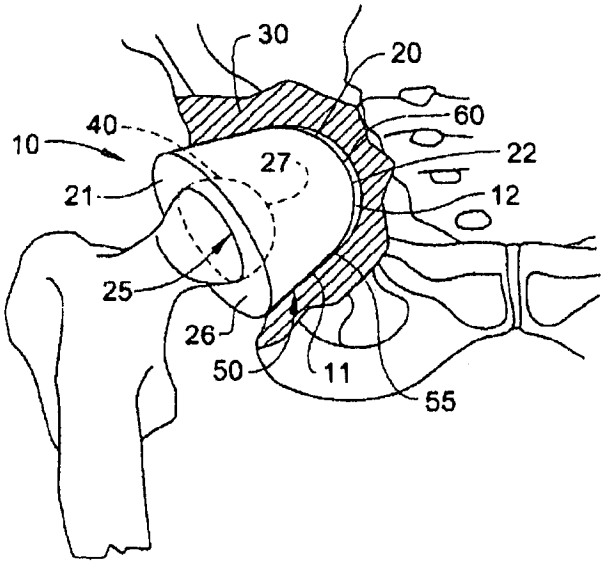
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FIG. 6

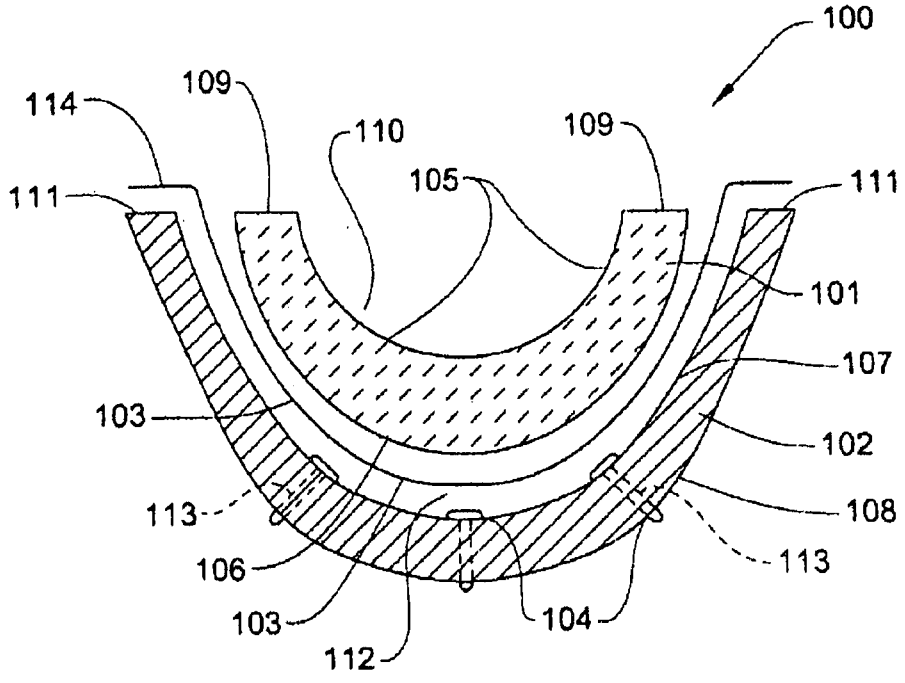
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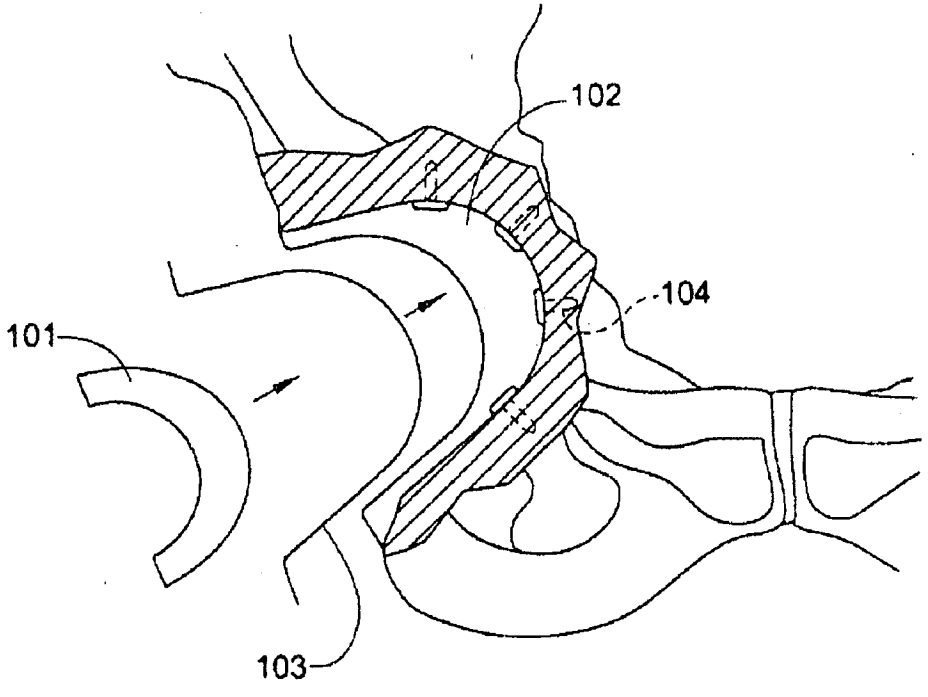
FIG. 7



ACETABULAR COMPONENT OF TOTAL HIP REPLACEMENT ASSEMBLY

This is a continuation-in-part of U.S. application Ser. No. 09/926,684 filed Mar. 4, 2002, now U.S. Pat. No. 6,712,857.

FIELD OF THE INVENTION

The present invention generally relates to a method and apparatus for use in surgical procedures involving arthroplasty. More specifically, it relates to a prosthetic socket portion of a joint replacement assembly, and a method for its insertion during arthroplasty. Particular reference is drawn to the apparatus in the form of an acetabular portion of a total hip replacement assembly.

BACKGROUND ART

The inclusion of the following description of the prior art is not an admission that the prior art is part of the common general knowledge in Australia.

It is well known to use prosthetic joint replacements in patients with various kinds of disorders affecting the joints, including degenerative disorders, such as severe osteoarthritis.

Over the years, a vast array of materials have been developed and utilised in the construction and manufacture of such prostheses. This is partly because the knowledge base regarding materials, and relevantly biocompatible materials, has been growing. It is also because, despite technological advances, there are a continuing number of complications associated with joint replacement prostheses with which surgeons and patients must grapple. As a result, surgeons and other inventors in the field have had, and are still challenged with, an ongoing quest to improve on the ease of insertion of the prostheses, to reduce the incidence of long and short term complications associated with using them, and to improve on the longevity of both the bio-prosthetic interface and the prostheses themselves.

Since the present invention refers specifically to a socket portion of a joint replacement assembly, and particularly refers to an acetabular component of a total hip replacement assembly, it is the latter which the following discussion briefly addresses.

The hip joint is comprised of the head of the femur articulating with the acetabulum. The acetabulum is generally cotyloidal in shape, and is often referred to as a "cup".

One of the first designs for the acetabular component of the hip joint, which was developed around 1960, was a hemisphere of metal internally lined with a plastics hemisphere, with the latter acting as the articulation surface. The metal was cemented into the bone and the liner was either pressed into the metal cup during the arthroplasty procedure, or was incorporated into the prosthesis during manufacture. In some later designs, the preferred method of securing the prosthesis was to screw it to the bone. However, while providing good fixation, screws have been found to lead to serious complications in the hip and are now not well regarded. Consequently, some of the more recent developments in acetabular prostheses have focused on new designs for their bone contacting surfaces. For example, some acetabular prostheses have been manufactured with a self-cutting thread on their bone contacting surface, while others have relied on press fitting along with cement, or a combination of surface roughening and hydroxyapatite.

In addition to considerable variation in the designs of the outer, or bone contacting, surfaces of acetabular prostheses, however, much research has been done in order to provide improved means of engaging the head of the femur (or prosthesis thereof). Forte (U.S. Pat. No. 5,062,853), for example, describes a particular construction for the inner aspect of the acetabular prosthesis which is particularly well adapted to receive and engage a corresponding prosthetic head of a femur.

Nevertheless, while prosthetic hip joint replacements have been shown to be incredibly beneficial for patients who require them, there are still a number of problems associated with their insertion for which further developments in the method and apparatus would be advantageous. The present invention is, most specifically, aimed at improving the bone contacting surface of acetabular prostheses, and therefore addresses many of the problems raised above.

DESCRIPTION OF THE INVENTION

In a first aspect, the present invention consists in a device for use in surgical procedures involving arthroplasty, the device including a socket member having a first surface and a second bone engaging surface, the first surface including at least a bearing surface adapted to receive a counter-component of a joint, and the bone engaging surface including a first portion having a shape, and at least a second portion having a different shape to that of the first portion.

In a second aspect, the present invention consists in a method of inserting a device according to the first aspect during an arthroplasty procedure, the method including the steps of:

a) bringing a surface of an appropriate joint orientation determining means into apposition with the exposed surface of the socket portion of a joint;

b) manipulating the joint orientation determining means so that the correct angular orientation for a socket portion of a joint replacement assembly is determined;

c) forming a hole into the bone adjacent the joint orientation determining means with a hole forming means, using said joint orientation determining means as a guide;

d) removing the joint orientation determining means from apposition with said exposed surface;

e) using the hole formed in step (c) as a guide, reaming an appropriately shaped and sized portion of bone from the bone forming the socket portion of the joint to a desired depth, thereby creating a reamed surface of bone;

f) bringing the bone engaging surface of a device according to the first aspect of the invention into contact with the reamed surface of bone; and

g) securing the device to the bone.

It is also noted that the use of Image Guided and Robotic Guidance surgical tools will also allow the accurate placement of the implant according to pre-operative planning and anatomical landmarks.

The device according to this invention may be used in a range of arthroplasty procedures, but is of particular applicability when used as a replacement for the acetabular component of a hip joint. By virtue of the nature of its function, preferred embodiments disclose that the socket member, as a whole, has a cotyloidal configuration with a longitudinal axis. The first surface of the socket member includes a bearing surface having a radius of curvature which is adapted to receive the counter-component of a joint, such as the head of the femur (or prosthesis thereof) in a hip joint. The socket member is, according to this invention, defined by a bone engaging surface. In accordance with its name, the bone engaging surface is adapted to engage a

bony surface comprising a portion of the joint which the device is intended to replace, such as the acetabulum in a hip joint.

Preferred embodiments of the invention disclose that the bone engaging surface of the socket member comprises at least a first and a second portion. In such embodiments, the first portion extends away from a circumferential join with the first surface of the socket member, and the second portion extends away from a circumferential join with the first portion to an extremity.

In further preferred embodiments, as the first portion extends away from its join with the first surface of the socket member, its cross-sectional diameter may decrease at a first rate. In such embodiments, the rate of change in cross-sectional diameter may be linear such that the first portion has a frusto-conical shape. In alternative embodiments, the rate of change may be logarithmic, exponential or may follow any other mathematical expression. In yet further alternative embodiments, the rate of change may itself change from one to another of these mathematical expressions as the first portion extends away from its join with the first surface.

Similarly, as the second portion extends away from its join with the first portion, its cross-sectional diameter may decrease at a second different rate to that of the cross-sectional diameter of the first portion. In preferred embodiments, the rate of change will comply with a mathematical expression which will cause the second portion to form a spherical section, and preferably, a hemi-section or a smaller section still. In alternative embodiments, the discussion of the mathematical expressions according to which the rate of change may comply from the paragraph above is also applicable to the rate of change for the cross-sectional diameter of the second portion.

As indicated above, however, in a preferred embodiment the first portion of the bone engaging surface is frusto-conical, while the second portion comprises a spherical section. Construction of the device according to either of these aspects of the invention, therefore, envisages the bone engaging surface of the socket member including any one of a plurality of combinations of portions having these, and other additional, shapes.

In some such embodiments of the invention, for example, the bone engaging surface includes a plurality of portions of different shapes, wherein at least one portion is frusto-conical, and another, comprises a spherical section; while in other embodiments, the bone engaging surface includes only two portions, each having one of the latter shapes. Indeed, embodiments of the invention wherein these two portions alone comprise the bone engaging surface are preferred. Consequently, the foregoing description outlines preferred structural combinations of the frusto-conical portion and portion comprising a spherical section for the bone engaging surface of the socket member.

In preferred embodiments, the bone engaging surface of the socket member is substantially hemispherical, having its rounded extremity formed by the portion of the bone engaging surface comprising a spherical section. In other words, in these particular embodiments, the frusto-conical portion of the bone engaging surface is oriented so that its smallest cross-sectional diameter meets, circumferentially, with the hemisphere formed by the portion comprising a spherical section; and its largest cross-sectional diameter meets, circumferentially, with the first surface of the socket member.

In alternative embodiments, the bone engaging surface comprises a frusto-conical portion, a portion comprising a spherical section, and a planar portion or a portion comprising a section of a larger sphere than the latter. Such embodiments disclose a similar configuration to that described in the preceding paragraphs. However, while the extremity of the bone engaging surface still has a substantially hemispherical surface, a portion of that surface is essentially planar.

As indicated earlier, the scope of this invention is not limited to the embodiments just described. There are multiple variations for the construction of the bone engaging surface having a plurality of portions, each with unique shapes, which fall within its scope. However, it is noteworthy that the incorporation of a bone engaging surface having a combination of a frusto-conical portion and portion comprising a spherical section may contribute considerably to the functionality and securability of the socket member.

In replacing a socket portion of a joint, the fixation of the socket member must be able to withstand rotational and other movement influencing forces created during articulation of the joint. While the means used to secure the socket member to the bone (see below) will be of substantial importance in this regard, having a frusto-conical shape for a portion of the bone engaging surface of the invention is also of particular value, as such a shape has excellent side rotational stabilising capacity.

In addition, such a shape helps to ensure that any compressive forces which the socket member applies to the bone during, for example, weight-bearing, is desirably distributed: with a frusto-conical shape, compression of the bone will be greatest at the largest cross-sectional diameter of the frusto-conical portion, namely, around the first surface of the socket member. The latter will, when the socket member has been inserted according to this invention, be located near the surface of the bone. It is desirable for the greatest compressive force which the socket member applies to the bone to be distributed at this location. This is because, if the greatest compression occurs in deeper regions of the bone, for example, those regions adjacent the extremity of the bone engaging surface of the socket member, then the surface bone is protected from stress and tends to weaken.

The capacity of a socket member according to this invention to distribute such compressive forces desirably is further augmented by the presence of a portion comprising a spherical section near or at the extremity of the bone engaging surface. In preferred embodiments, the bone engaging surface of the socket member, despite being comprised of a plurality of portions each having unique shapes, is continuous, in that the meeting loci of these portions are not interrupted, or constructed, by a sharp edge or a 'step'. When the portion comprising a spherical section is at the extremity of the bone engaging surface it acts as a further means to ensure that no such edge or step is in contact with the surrounding bone. The value of ensuring as much, especially near the extremity of the bone engaging surface, is that an edge-like or step-like protrusion would, during the application of weight-bearing compressive forces, act as a stress riser on the bone. For the reasons already outlined, among others, this is not desirable.

Preferred embodiments also disclose that a bearing surface is located at the first surface of the socket member. Such a bearing surface, has the capacity to receive the counter-component of a joint such as the head of the femur (or prosthesis thereof) in a hip joint.

In some such embodiments of the invention, the first surface of the socket member is comprised of a relatively planar surface into which the bearing surface forms an indent. Because the bearing surface receives the counter-component of the joint, the materials used in the construc-

tion of the invention warrant discussion: while there are no particular limitations on the materials to be used in the manufacture of the socket member, it is replacing a bony component of a joint, and must, therefore, have similar characteristics in terms of strength and resilience. Various metals, as well as ceramics, or carbon fibre may all be appropriate. As an integral component of the socket member, the bearing surface will also be made of such a material. However, since this surface of the socket member represents the articulating surface of the joint, it is desirable to use a high-wear resistance material such as polyethylene or ceramics. Accordingly, in preferred embodiments of the invention, a shell being made of polyethylene, or similar appropriate material, and having a shape which corresponds with the bearing surface is machine fitted to the latter. Note, however, that although machine fitting provides for a tighter fit and a convenient form of manufacture, it is not a requisite component of this invention that the shell be fitted by machine. Indeed, any appropriate method of fitting the shell, including for example, by known methods of clipping it into position, falls within the scope of this invention.

It is further noteworthy that as the bearing surface comes under load, there may be relative movement, or micro-motion, between the shell and the bearing surface of the socket member to which it is fitted. This can generate wear particles. In order to render less likely such generation, preferred embodiments of the invention disclose that an interface between the bearing surface of the socket member and the shell is surface-coated with a material, such as titanium nitrate or titanium carbide. Alternatively, the surface may be roughened in order to reduce relative motion, whereby the two materials "key in" to each other.

Additionally disclosed is a method for inserting a socket member according to the invention during an arthroplasty procedure. Although not required in many cases, it may initially be necessary for the surgeon to perform a small hemispherical ream into the bone forming the socket portion of the joint. It may be appropriate to do so in cases where this part of the joint has undergone severe pathological degeneration.

Nevertheless, whether or not the decision is made to perform the small hemispherical ream, the method generally includes the steps of:

a) bringing a surface of an appropriate joint orientation determining means into apposition with the exposed surface of the socket portion of the joint. For the purposes of this disclosure, a "joint orientation determining means" refers to an appropriate device which can be used to determine the correct orientation for a replacement prosthesis;

b) manipulating the joint orientation determining means so that the correct angular orientation for a socket portion of a joint replacement assembly is determined.

Such determination is critical, both for ensuring the best alignment and also for finding a position which provides the least likelihood of dislocation. Determination of the correct angular orientation may be achieved by having reference to appropriate anatomical landmarks, by simple visualisation, or with whatever method is preferred by the surgeon;

c) forming a hole into the bone adjacent the joint orientation determining means with a hole forming means, such as a drill bit, using said joint orientation determining means as a guide. In preferred embodiments of the invention, the joint orientation determining means is pre-prepared with a hole designed to receive the hole forming means. In alternative embodiments, it may not be;

d) removing the joint orientation determining means from apposition with the exposed surface of bone;

e) using the hole formed in (c) as a guide, reaming an appropriately shaped and sized portion of bone from the bone forming the socket portion of the joint to a desired depth, thereby creating a reamed surface of bone. In preferred embodiments, the reamed surface should extend to a depth slightly beyond the depth attained, according to this invention, by the extremity of the bone engaging surface of a fully inserted socket member.

f) bringing the bone engaging surface of a socket member according to the invention into contact with the reamed surface of bone; and

g) securing the socket member to the bone. In preferred embodiments, the socket member is press fit, and not threaded. While a socket member having a thread is not outside the scope of this invention, the press fit solution is preferred as it significantly decreases the technical complexity of insertion. As explained in (e) above, when the socket member is fully inserted, preferred embodiments disclose that there should be a small space between the extremity of the bone engaging surface and the reamed surface of bone. This space provides room to allow for a small amount of subsidence of the socket member when it is subjected to compressive forces, for example, during weight-bearing.

Reinforced fixation of the socket member in the correct position may additionally be achieved by cement, by a combination of roughening and hydroxyapatite, or by any other appropriate means.

The socket member, according to this invention, is now ready to receive the counter-component of the joint, or a prosthesis thereof.

More specifically, in cases where a socket member according to the invention will be used to replace the acetabular portion of a hip joint, similar commentary regarding the steps above is appropriate, but in summary, the method includes the following:

a) bringing a convex surface of a hemispherical cup (an appropriate joint determining means for hip joint arthroplasty) into apposition with the exposed surface of the acetabulum;

b) manipulating the hemispherical cup so that the correct angular orientation for an acetabular portion of a total hip replacement assembly is determined;

c) forming a hole into the bone adjacent the hemispherical with a hole forming means, such as a drill bit, using said hemispherical cup as a guide;

d) removing the hemispherical cup from apposition with the exposed surface of the acetabulum;

e) using the hole drilled in (c) as a guide, reaming an appropriately sized frusto-conical portion of bone from the acetabulum to a desired depth, thereby creating a reamed surface of bone;

f) bringing a socket member according to this invention into contact with the reamed surface of bone; and

g) securing the socket member to the bone.

The socket member is now ready to receive the head of the femur, or a prosthesis thereof.

In accordance with this latter description, pertaining to a method for inserting a device according to the invention in an arthroplasty procedure on the hip joint, a further aspect to the invention is disclosed:

In a further aspect, the present invention consists in a method of inserting a device according to the first aspect during an arthroplasty procedure involving the hip joint, wherein the bone engaging surface is comprised of a first frusto-conical portion and at least a second portion, wherein the second portion includes a spherical section, the method including the steps of:

a) bringing a convex surface of a hemispherical cup into apposition with the exposed surface of the acetabulum;

b) manipulating the hemispherical cup so that the correct angular orientation for an acetabular portion of a hip replacement assembly is determined;

c) forming a hole in the acetabulum with a hole forming means, using the hemispherical cup as a guide;

d) removing the hemispherical cup from apposition with said exposed surface of acetabulum;

e) using the hole drilled in (c) as a guide, reaming an appropriately sized frusto-conical portion of bone from the acetabulum to a desired depth, thereby creating a reamed surface of bone;

f) bringing a device according to this aspect of the invention into contact with the reamed surface of bone; and

g) securing the device to the bone.

A significant advantage of the present invention is that in the event that an error is made while carrying out step (e), and the ream is found to be in the wrong direction, the option is still available to then use a hemispherical reamer to slightly enlarge the reamed surface of bone, with minimal extra bone resection. In this instance, it will be possible to still position a hemispherical socket member against the reamed hemispherical surface and secure it to the bone. Thus, the present invention additionally offers a satisfactory avenue for dealing with initial errors of alignment in reaming the appropriately sized frusto-conical portion of bone.

As noted above, the device of the present invention may be a one-piece unit or optionally comprise two pieces. In the latter, the device may include a first component that sits within a reamed section of bone and receives a cup component therewithin. The first component is typically made from a biocompatible metal and the cup component from a polyethylene of ceramic material. The cup component receives a counter component of a joint.

Typically, the first component is secured to the bone of a patient by screws, thus requiring screw holes to receive the screws. When the polyethylene or ceramic cup component is placed within the first component and the device subjected to the fluid pressures experienced during walking, micro-movement between the two components may occur. This may lead to the production of debris that can migrate through the screw holes within the first component and penetrate the bone, resulting in bone loss.

In a further aspect of the invention, therefore, there is provided a device for use in a surgical procedure involving arthroplasty, the device including a bearing member at least partially received within a recess of a bone engaging member and a liner positioned at least partially between said bearing member and said bone engaging member to substantially cover at least one bone securing means of said bone engaging member.

In another aspect, the present invention comprises a liner for an arthroplasty device, said liner at least partially positionable between a bearing member and a bone engaging member of the arthroplasty device to substantially cover at least one bone securing means of the bone engaging member.

The bearing member may comprise a first surface to receive a counter component of a joint and a second surface that is engageable with said liner. The bone engaging member may have a liner engaging surface and a bone engaging surface.

The first surface of the bearing member may comprise a relatively planar surface into which is formed an indent to receive a ball portion of a joint.

The second surface of the bearing member may form a circumferential join with the first surface and extend away from said circumferential join to define a substantially hemispherical or frustoconical portion.

The bone engaging member typically also has a relatively planar surface into which is formed the recess, said recess defined by the liner engaging surface and said planar surface forming a rim around the recess. The recess receives the bearing member of the device.

The liner of the device preferably substantially conforms with the contour of the liner engaging surface of the bone engaging member.

The at least one bone securing means may comprise at least one and preferably a plurality of screw holes through which screws may threaded. In use, the bone engaging member is positioned appropriately within a reamed portion of bone and the screws threaded through the holes and into the bone of the patient to secure the bone engaging member to the bone.

The liner typically fully covers the screw hole(s) and the screw(s) when the bone engaging member is secured to the bone of the patient. In a preferred embodiment, at least a portion of the liner extends beyond the liner engaging surface of the bone engaging member. Typically, the portion of the liner that extends beyond the liner engaging surface comprises a lip member that engages the rim of the bone engaging member. In this embodiment, the liner fully seals the space between the bearing member and the bone engaging member thereby reducing micromovement between the two and the build up of wear debris when the device is in use. By fully sealing the space between the two components, any wear debris is also prevented from migrating into the bone via the screw holes of the bone engaging member.

Preferably, the liner is made from a biocompatible material including titanium. The bearing member is typically made from a polyethylene or ceramic material and the bone engaging member is preferably made from a biocompatible metal. Optionally, the bone engaging member may be made from a graded material including a functionally graded or biologically graded material, or reinforced hydroxyapatite.

The liner of the device preferably has a diameter of less than 1 mm and more preferably less than 0.5 mm. This embodiment is particularly advantageous in that the liner is sufficiently thin so as to not significantly increase the thickness of the device and so as to deform and cold weld to the bone engaging member of the device.

In a still further aspect, there is provided a method of inserting a device during an arthroplasty procedure, the device including a bearing member at least partially receivable within a recess of the bone engaging member and a liner positioned at least partially between said bearing member and said bone engaging member to substantially cover at least one bone securing means of the bone engaging member, said method comprising:

(a) positioning the bone engaging member within a suitably reamed portion of bone of a patient;

(b) fixing said bone engaging member to the bone of the patient via said at least one bone securing means;

(c) positioning the liner adjacent or in engagement with said bone engaging member;

(d) positioning the bearing member within the recess of the bone engaging member and securing the bearing member to the bone engaging member such that the liner is positioned therebetween.

Typically, the liner is secured to a liner engaging surface of the bone engaging member prior to positioning of the

bearing member. In this regard, the liner may be cold welded to the bone engaging member.

The bone engaging member is typically fixed to the bone of a patient by a screw or a plurality of screws. In this regard, the liner is preferably positioned such that it fully covers said screw or plurality of screws.

The bearing member may be secured to the bone engaging member by press fit.

Typically, the device of the present invention replaces an acetabular portion of a joint including a hip joint of a patient.

BRIEF DESCRIPTION OF THE DRAWINGS

By way of example, preferred embodiments of the invention are described with reference to the accompanying drawings in which:

FIG. **1** is a schematic representation of a prosthetic total hip replacement assembly, as inserted, following arthroplasty to the right hip;

FIG. **2***a* is a cross-sectional view of a socket member according to a preferred embodiment of the invention;

FIG. **2***b* is a diagrammatic representation of a top view of the socket member in FIG. **2***a*, illustrating the first surface of that socket member;

FIG. **3***a* is a perspective view of a socket member according to the preferred embodiment of the invention illustrated in FIG. **2***a*;

FIG. **3***b* is a cross-sectional view of the socket member of FIG. **3***a*;

FIG. **4***a* is a perspective view of a socket member according to another embodiment of this invention;

FIG. **4***b* is a cross-sectional view of the socket member of FIG. **4***a*;

FIG. **5***a* is an exploded perspective view illustrating the relative positions of the reamed surface of the acetabulum, the socket member according to a preferred embodiment of the invention, and the head of the femur (or prosthesis thereof), as they are each about to be inserted into the right hip;

FIG. **5***b* is a perspective view illustrating the componentry shown in FIG. **5***a* as correctly inserted into the right hip;

FIG. **6** is a cross-sectional view of a device according to a further aspect of the invention; and

FIG. **7** is a perspective view of positioning of the components of the device depicted in FIG. **6** during a hip arthroplasty procedure.

PREFERRED MODE OF CARRYING OUT THE INVENTION

The device according to this invention may be used in a range of arthroplasty procedures, but is of particular applicability to arthroplasty procedures involving the hip joint (see FIG. **1**).

The socket member **10** has a bone engaging or contacting surface **20** that is comprised of a first portion which is frusto-conical **11**, and a second portion comprising a spherical section **12**. Consequently, the foregoing description outlines preferred structural combinations of the frusto-conical portion **11** and portion comprising a spherical section **12** for the bone contacting surface **20** of the socket member **10**.

The bone contacting surface **20** of the socket member **10** extends away from the socket member's first surface **21** in such a way that the cross-sectional diameter of the bone contacting surface **20** (in a plane substantially perpendicular to the longitudinal axis) diminishes at one rate for the frusto-conical portion **11**, and diminishes at a second different rate for the second portion comprising a spherical section **12** to a rounded extremity **22**. In other words, the frusto-conical portion **11** of the bone contacting surface **20** is oriented so that its smallest cross-sectional diameter meets, circumferentially, with the hemispherical section formed by the portion comprising a spherical section **12**; and its largest cross-sectional diameter meets, circumferentially, with the first surface **21** of the socket member **10**.

As indicated earlier, the scope of this invention is not limited to the embodiments just described. There are multiple variations for the construction of the bone contacting surface **20** having a plurality of portions, each with unique shapes, which fall within its scope. However, as noted in the description of the invention the incorporation of a bone contacting surface **20** having a combination of a frusto-conical portion **11** and portion comprising a spherical section **12** may contribute considerably to the functionality and securability of the socket member **10**.

In replacing a socket portion of a joint, the fixation of the socket member **10** must be able to withstand rotational and other movement forces created during articulation of the joint. Having a frusto-conical shape for a portion **11** of the bone contacting surface **20** of the invention is also of particular value, as such a shape has excellent side rotational stabilising capacity.

In addition, such a shape helps to ensure that any compressive forces which the socket member **10** applies to the bone during, for example, weight-bearing, is desirably distributed: with a frusto-conical shape **11**, compression of the bone will be greatest at the largest cross-sectional diameter of the frusto-conical portion **11**, namely, at around the join with the first surface **21** of the socket member **10**. The latter will, when the socket member **10** has been inserted according to this invention, be located near the surface of the bone **30**. It is desirable for the greatest compressive force which the socket member **10** applies to the bone **30** to be distributed at this location. This is because, if the greatest compression occurs in deeper regions of the bone **30**, for example, those regions adjacent the extremity **22** of the bone contacting surface **20** of the socket member **10**, then the surface bone **30** is protected from stress and tends to weaken.

The capacity of a socket member **10** according to this invention to distribute such compressive forces desirably is further augmented by the presence of a portion comprising a spherical section **12** near or at the extremity **22** of the bone contacting surface **20**. In preferred embodiments, the bone contacting surface **20** of the socket member **10**, despite being comprised of two portions each having unique shapes (**11** and **12** respectively), is continuous, in that the meeting loci of these portions **11** and **12** are not interrupted, or constructed, by a sharp edge or a 'step'. When the portion comprising a spherical section **12** is at the extremity **22** of the bone contacting surface **20** it acts as a further means to ensure that no such edge or step is in contact with the surrounding bone **30**. The value of ensuring as much, especially near the extremity **22** of the bone contacting surface **20**, is that an edge-like or step-like protrusion would, during the application of weight-bearing compressive forces, act as a stress riser on the bone. For the reasons already outlined, among others, this is not desirable.

The bearing surface **25** is located at the first surface **21** of the socket member **10**. Such a bearing surface **25**, has the capacity to receive the counter-component of a joint such as the head of the femur **40** (or prosthesis thereof) in a hip joint. In fact, the first surface **21** of the of the socket member **10**

is comprised of a relatively planar annular surface **26** into which the bearing surface **25** forms an indent.

While there are no particular limitations on the materials to be used in the manufacture of the socket member **10**, it is replacing a bony component of a joint, and must, therefore, have similar characteristics in terms of strength and resilience. As already explained, various metals, as well as ceramics, or carbon fibre may all be appropriate. As an integral component of the socket member **10**, the bearing surface **25** will also be made of such a material. However, since this surface **25** of the socket member **10** represents the articulating surface of the joint, it is desirable to use a material of high wear resistance such as polyethylene or ceramics. Accordingly, a shell **27** being made of polyethylene, or similar appropriate material, and having a shape which corresponds with the bearing surface **25** is, in the depicted embodiment, machine fitted to the latter. However, although machine fitting provides for a tighter fit and a convenient form of manufacture, it is not a requisite component of this invention that the shell **27** be fitted by machine. Indeed, any appropriate method of fitting the shell **27**, including for example, by known methods of clipping it into position, falls within the scope of this invention.

In addition, as the bearing surface **25** comes under load, there may be relative movement, or micro-motion, between the shell **27** and the bearing surface **25** of the socket member **10** to which it is fitted. This can generate wear particles. In order to render less likely such generation, the interface between the bearing surface **25** of the socket member **10** and the shell **27** is surface-coated with a material, such as titanium nitrate or titanium carbide.

Also disclosed is a method for inserting a socket member **10** according to the invention as a prosthetic replacement for the acetabular portion of a hip joint (see FIG. 1). Although not required in many cases, it may initially be necessary for the surgeon to perform a small hemispherical ream into the acetabulum **50**. It may be appropriate to do so in cases where this part of the joint has undergone severe pathological degeneration. Nevertheless, whether or not the decision is made to perform the small hemispherical ream, the method generally includes the steps of:

a) bringing a convex surface of a hemispherical cup (not shown) (an appropriate joint determining means for hip joint arthroplasty) into apposition with the exposed surface of the acetabulum **50**;

b) manipulating the hemispherical cup (not shown) so that the correct angular orientation for an acetabular portion of a total hip replacement assembly is determined. Such determination is critical, both for ensuring the best alignment and also for finding a position which provides the least likelihood of dislocation. Determination of the correct angular orientation may be achieved by having reference to appropriate anatomical landmarks, by simple visualisation, or with whatever method is preferred by the surgeon;

c) forming a hole (not shown) into the bone **30** adjacent the hemispherical cup (not shown) with a drill bit (not shown), using said hemispherical cup as a guide. The hemispherical cup is normally pre-prepared with a hole designed to receive the drill bit;

d) removing the hemispherical cup (not shown) from apposition with the exposed surface of the acetabulum **50**;

e) using the hole drilled in (c) as a guide, reaming an appropriately sized frusto-conical portion of bone from the acetabulum to a desired depth, thereby creating a reamed surface **55** of bone **30**. The reamed surface **55** should extend to a depth slightly beyond the depth attained, according to this invention, by the extremity **22** of the bone contacting surface **20** of a fully inserted socket member **10**.

f) bringing a socket member **10** according to this invention into contact with the reamed surface **55** of bone **30**; and

g) securing the socket member **10** to the bone **30**. In the depicted embodiment, the socket member **10** is press fit, and not threaded. As explained in (e) above, when the socket member **10** is fully inserted, there should be a small space **60** between the extremity **22** of the bone contacting surface **20** and the reamed surface **55** of bone **30**. This space **60** provides room to allow for a small amount of subsidence of the socket member **10** when it is subjected to compressive forces, for example, during weight-bearing.

Reinforced fixation of the socket member **10** in the correct position may additionally be achieved by cement, by a combination of roughening and hydroxyapatite, or by any other appropriate means.

The socket member **10**, according to this invention, is now ready to receive the head of the femur **40**, or a prosthesis thereof.

In a further aspect of the invention, device **100** comprises a bearing member **101** that is received in a recess of a bone engaging member **102**. The device also has a liner **103** positioned between the bearing member **101** and the bone engaging member **102** to substantially cover bone securing means **104** of the bone engaging member **102**.

The bearing member comprises a first surface **105** to receive a counter component of a joint and a second surface **106** that is engageable with the liner **103**. The bone engaging member has a liner engaging surface **107** and a bone engaging surface **108**.

The first surface **105** of the bearing member comprises a relatively planar surface portion **109** into which is formed an indent **110** to receive a ball portion of a joint.

The bone engaging member **102** also has a relatively planar surface portion **111** into which is formed the recess **112**, said recess **112** defined by the liner engaging surface **107** and said planar surface portion **111** forming a rim around the recess. The recess receives the bearing member **101**.

The liner **103** substantially conforms with the contour of the liner engaging surface **107** of the bone engaging member **102**.

The bone securing means **104** comprises at least one and preferably a plurality of screw holes through which screws **113** are threaded. In use, the bone engaging member **102** is positioned appropriately within a reamed portion of bone and the screws **113** threaded through the holes and into the bone of the patient to secure the bone engaging member **102** to the bone.

The liner typically fully covers the screw holes and the screws **113** when the bone engaging member **102** is secured to the bone of the patient. In a preferred embodiment, at least a portion **114** of the liner **103** extends beyond the liner engaging surface **107** of the bone engaging member **102**. Typically, the portion **114** of the liner **103** that extends beyond the liner engaging surface comprises a lip member that engages the rim of the bone engaging member. In this embodiment, the liner fully seals the space between the bearing member **101** and the bone engaging member **102** thereby reducing micromovement between the two and the build up of wear debris when the device is in use. By fully sealing the space between the two components, any wear debris is also prevented from migrating into the bone via the screw holes of the bone engaging member.

Preferably, the liner is made from a biocompatible material including titanium. The bearing member is typically

made from a polyethylene or ceramic material and the bone engaging member is preferably made from a biocompatible metal. Optionally, the bone engaging member may be made from a graded material including a functionally graded or biologically graded material, or reinforced hydroxyapatite.

In use, the bone engaging member **102** is positioned within a suitably reamed portion of bone of a patient. The bone engaging member **102** is then fixed to the bone of the patient via screws **113**. The liner **103** is then positioned adjacent or in engagement with said bone engaging member **102** and the bearing member **101** positioned within the recess **112** of the bone engaging member **102**. The bearing member **101** is then secured to the bone engaging member **102** such that the liner **103** is positioned therebetween.

It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the invention as shown in the specific embodiments without departing from the spirit or scope of the invention as broadly described. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive.

The invention claimed is:

1. A device for use in surgical procedures involving arthroplasty, the device comprising:

a socket member comprising:

a first surface adapted to receive a counter component of a joint, and

a bone engaging surface comprising:

a first surface portion that extends away from a circumferential join with the first surface; and

a second surface portion that extends away from a the first surface portion to an extremity;

wherein the first surface portion is configured such that a cross-sectional diameter of the first surface portion decreases at a first rate as the first surface portion extends away from the circumferential join with the first surface, and the second surface portion is configured such that a cross-sectional diameter of the second surface portion decreases at a second rate, the second rate being different from the first rate, and

wherein the first surface portion and the second surface portion are arranged relative to each other such that the bone engaging surface is devoid of a step or an edge at a meeting loci of the first surface portion and the second surface portion.

2. The device of claim **1**, wherein the bone engaging surface being devoid of a step or a corner prevents the application of undue stress to the surrounding bone.

3. The device of claim **1**, when used as a replacement for the acetabular component of a hip joint.

4. The device of claim **1**, wherein the first rate of decrease in cross-sectional diameter of the socket member is linear.

5. The device of claim **1**, wherein the second rate of decrease in cross-sectional diameter of the socket member is logarithmic or exponential.

6. The device of claim **1**, wherein the second rate of decrease in cross-sectional diameter of the socket member varies as the second surface portion extends away from a line of meeting with the first surface portion and the second surface portion.

7. The device of claim **1**, wherein the first surface portion is defined by a frustoconical section of the socket member and the second surface portion is defined by a spherical section of the socket member.

8. The device of claim **7**, wherein the frusto-conical section of the socket member is oriented so that its smallest cross-sectional diameter meets, circumferentially, with a hemisphere formed by the spherical section and its largest cross-sectional diameter meets, circumferentially, with the first surface of the socket member.

9. The device of claim **1**, wherein the socket member is cotyloidal in configuration with a longitudinal axis.

10. The device of claim **1**, wherein the first surface of the socket member comprises a relatively planar surface into which the bearing surface forms an indent.

11. The device of claim **1** wherein the socket member is made from any one of the group comprising metals, ceramics, or carbon fibre.

12. The device of claim **1**, wherein the bearing surface of the socket member is made from a material of higher wear resistance relative the remaining material of the socket member.

13. The device of claim **12**, wherein the bearing surface is made from polyethylene or a ceramic material.

14. The device of claim **1**, wherein a shell of polyethylene having a shape which corresponds with the bearing surface is fitted to the bearing surface.

15. The device of claim **14**, wherein an interface formed between the bearing surface of the socket member and the shell is surface-coated with titanium nitrate or titanium carbide.

16. A device for use in surgical procedures involving arthroplasty, the device comprising:

a bone engaging member configured to be secured to a bone with at least one bone securing means;

a bearing member configured to be at least partially received within a recess of the bone engaging member; and

a liner configured to be positioned at least partially between the bearing member and the bone engaging member to substantially cover the at least one bone securing means of the bone engaging member;

wherein the bone securing member comprises:

a liner engaging surface; and

a bone engaging surface, comprising:

a first surface portion that extends away from a circumferential join with the liner engaging surface; and

a second surface portion that extends away from a the first surface portion to an extremity;

wherein the first surface portion is configured such that a cross-sectional diameter of the first surface portion decreases at a first rate as the first surface portion extends away from the circumferential join with the first surface, and the second surface portion is configured such that a cross-sectional diameter of the second surface portion decreases at a second rate, the second rate being different from the first rate, and

wherein the first surface portion and the second surface portion are arranged relative to each other such that the bone engaging surface is devoid of a step or an edge at a meeting loci of the first surface portion and the second surface portion.

17. The device of claim **16**, wherein the bearing member has a first surface configured to receive a counter component of a joint and a second surface that is configured to be engageable with the liner.

18. The device of claim **17**, wherein the first surface of the bearing member comprises a relatively planar surface into which is formed an indent configured to receive a ball portion of a joint.

19. The device of claim **17**, wherein the second surface of the bearing member forms a circumferential join with the

first surface and extends away from the circumferential join to define a substantially hemispherical or frustoconical portion.

20. The device of claim **16**, wherein the bone engaging member has a relatively planar surface into which is formed the recess, the recess defined by the liner engaging surface, the planar surface forming a rim around the recess.

21. The device of claim **16**, wherein the at least one bone securing means of the bone engaging member comprises at least one screw hole to receive a screw for securing the bone engaging member to the bone of a patient.

22. The device of claim **21**, wherein the liner substantially conforms with the contour of the liner engaging surface of the bone engaging member and covers the at least one screw hole of the bone engaging member.

23. The device of claim **22**, wherein at least a portion of the liner extends beyond the liner engaging surface of the bone engaging member.

24. The device of claim **23**, wherein said portion of the liner that extends beyond the liner engaging surface comprises a lip member that engages the rim of the bone engaging member.

25. The device of claim **21**, wherein when the device is in use, the liner prevents the migration of wear debris to the bone via the at least one screw hole of the bone engaging member.

26. The device of claim **25**, wherein when the device is in position within a patient, the liner also reduces relative movement between the bearing member and the bone engaging member thereby reducing the amount of wear debris produced as a result of said relative movement.

27. The device of claim **16**, wherein the liner is made from a biocompatible material including titanium.

28. The device of claim **16**, wherein the bearing member is made from a polyethylene or ceramic material.

29. The device of claim **16**, wherein the bone engaging member is made from a metal or plastics material.

30. The device of claim **16**, wherein the liner has a thickness of less than 1 mm.

31. The device of claim **30**, wherein the liner has a diameter of less than 0.5 mm.

* * * * *

UNITED STATES
DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA
SAN DIEGO DIVISION

 # 152200 - TC
*** * C O P Y * ***
June 23, 2008
16:36:38

Civ Fil Non-Pris
USAO #.: 08CV1117
Judge..: WILLIAM Q HAYES
Amount.: $350.00 CK
Check#.: BC1065

Total-> $350.00

FROM: ADVACNED SURGICAL DESIGNS
VS.
PORTLAND ORTHAPEDICS

ORIGINAL

JS 44 (Rev. 12/07)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

I. (a) PLAINTIFFS
Advanced Surgical Design and Manufacture Limited, an Australian Co.

(b) County of Residence of First Listed Plaintiff _____
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorney's (Firm Name, Address, and Telephone Number)
See Attached

DEFENDANTS
Portland Orthopaedics Pty. Ltd., an Australian Co.. Portland Orthopaedics Inc., a Michigan Corp.

FILED
08 JUN 23 PM 4:34
CLERK, U.S. DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA
BY DEPUTY

County of Residence of First Listed Defendant _____
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED.

Attorneys (If Known)

08 CV 1117 WQH NLS

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff
- ☒ 3 Federal Question (U.S. Government Not a Party)
- ☐ 2 U.S. Government Defendant
- ☐ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☒ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT (Place an "X" in One Box Only)

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excl. Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury

PERSONAL INJURY
- ☐ 362 Personal Injury - Med. Malpractice
- ☐ 365 Personal Injury - Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 444 Welfare
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 440 Other Civil Rights

PRISONER PETITIONS
- ☐ 510 Motions to Vacate Sentence

Habeas Corpus:
- ☐ 530 General
- ☐ 535 Death Penalty
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition

FORFEITURE/PENALTY
- ☐ 610 Agriculture
- ☐ 620 Other Food & Drug
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 630 Liquor Laws
- ☐ 640 R.R. & Truck
- ☐ 650 Airline Regs.
- ☐ 660 Occupational Safety/Health
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Mgmt. Relations
- ☐ 730 Labor/Mgmt.Reporting & Disclosure Act
- ☐ 740 Railway Labor Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Empl. Ret. Inc. Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 463 Habeas Corpus - Alien Detainee
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☒ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
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- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 810 Selective Service
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 875 Customer Challenge 12 USC 3410
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 892 Economic Stabilization Act
- ☐ 893 Environmental Matters
- ☐ 894 Energy Allocation Act
- ☐ 895 Freedom of Information Act
- ☐ 900Appeal of Fee Determination Under Equal Access to Justice
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN (Place an "X" in One Box Only)
☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district (specify) ☐ 6 Multidistrict Litigation ☐ 7 Appeal to District Judge from Magistrate Judgment

VI. CAUSE OF ACTION
Cite the U.S. Civil Statute under which you are filing **(Do not cite jurisdictional statutes unless diversity)**:
35 U.S.C. Section 271 et seq.
Brief description of cause:
Patent Infringement

VII. REQUESTED IN COMPLAINT: ☐ CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23 **DEMAND $** CHECK YES only if demanded in complaint: **JURY DEMAND:** ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY (See instructions): JUDGE _____ DOCKET NUMBER _____

DATE June 23, 2008 SIGNATURE OF ATTORNEY OF RECORD Nicola A. Pisano (RCW)

FOR OFFICE USE ONLY

RECEIPT # 152800 AMOUNT $350 APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

TAC 6/23/08

CR

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